

REMARKS

Favorable reconsideration is respectfully requested in light of the above amendments and the following remarks. Claim 6 has been amended to correct its dependency. This minor amendment does not raise any new issues and thus should not be construed as a valid reason to refuse entry of this After-Final Amendment.

Rejections under 35 U.S.C. §103

Applicants respectfully traverse the Examiner's rejection of claims 1, 4, 6, 8, 11-12 and 16-17 under 35 U.S.C. §103(a) as unpatentable over Song (WO 2005/016399) in view of Klokke-Bethke et al. (U.S. Patent No. 5,335,769).

As a preliminary matter, Applicants wish to address an error made by the Examiner. The Examiner has referenced page 20, lines 7-25 of the instant specification as allegedly defining isothermal drying to include freeze-drying and vacuum-drying. A portion of this section is reproduced below:

Both, temperature and pressure are needed to be set carefully to ensure that the solution remains in the liquid state throughout drying. Preferably the drying process is carried out in a freeze-dryer to maintain and control the defined drying parameters during the drying process. Preferably the drying process is carried out in an oxygen free environment, e.g. by means of venting the drying chamber with Nitrogen, Argon etc. (emphasis added, Paragraph [0071] of published application)

One of skill in the art will appreciate that the application does not describe using a freeze-drying process. Rather, the application describes utilizing a freeze-dryer apparatus to carry out isothermal drying. The freeze-dryer apparatus is used in order to maintain and control the defined drying parameters during the drying process. This is not the same as conducting freeze-drying.

Moreover, conducting the drying process in an oxygen free environment does not mean doing so in a vacuum, or conducting vacuum drying. Rather, the application suggests conducting the recited isothermal drying process in what one of skill will recognize as being an inert atmosphere of nitrogen or argon, for example. The Examiner has improperly

characterized the application, concluding that an isothermal drying process includes freeze drying processes or vacuum drying processes.

Moreover, there are in fact distinct differences between the isothermal drying process referenced in the instant claims and a freeze-drying process such as that used by the secondary reference. In isothermal drying, the substance is heated to evaporate the liquid and the evaporated liquid is cooled. However, the liquid containing the substance to be coated onto the carrier is not frozen (see page 20, lines 17-19 of the application as filed). In freeze-drying, however, the substance to be lyophilized is frozen, kept at a freezing temperature, and then heated. Freeze drying and isothermal drying are simply not the same process.

As admitted by the Examiner, Song does not describe the claimed isothermal drying step. Indeed, and as discussed in the previous Amendment, Song teaches drying a coated device in an oven. There is no discussion within Song that this drying process is less than optimal or otherwise in need of improvement, and thus one of skill in the art would not be motivated to alter Song's drying process.

Further, Klokke-Bethke cannot be combined with Song because it teaches away from doing so. In particular, Klokke-Bethke use a silicone-coated glass for lyophilization. The reference warns, however (see column 2, lines 54-60) that the use of a silicone-coated glass is unpredictable. In other words, the reference teaches that it would be unpredictable what would happen if a siliconized container becomes the packaging container, i.e., what would happen if a product is dried in a siliconized coating container.

Further, Klokke-Bethke is directed to freeze-drying a pharmaceutically active substance. This reference is silent as to drying a medical device that has been coated with an active substance.

For at least these reasons, claim 1 is patentable over the combination of these references. The dependent claims include the elements of claim 1 and therefore are patentable for at least the same reasons. The dependent claims also include further distinguishing features. Withdrawal of the rejection is requested.

Applicants respectfully traverse the Examiner's rejection of claims 9, 13, 48 and 52-53 under 35 U.S.C. §103(a) as unpatentable over Song (WO 2005/016399) in view of Klokckers-Bethke et al. (U.S. Patent No. 5,335,769) and further in view of Kohnert et al. (WO 2003/043673).

Claim 1, from which the other claims depend, is distinguished above as being patentable over Song and Klokckers-Bethke. Kohnert et al. does not remedy the noted shortcomings of these references because Kohnert et al. describes a dip coating method in which the object being coated is dried after removal from the coating solution. Specifically, Kohnert et al. report, at pages 6 and 7, a coating process in which a device is coated and then is subsequently dried outside of the coating solution.

Thus, claim 1 is patentable over the combination of these references. The dependent claims include the elements of claim 1 and therefore are patentable for at least the same reasons. The dependent claims also include further distinguishing features. Withdrawal of the rejection is requested.

Applicants respectfully traverse the Examiner's rejection of claim 15 under 35 U.S.C. §103(a) as unpatentable over Song (WO 2005/016399) in view of Klokckers-Bethke et al. (U.S. Patent No. 5,335,769) and further in view of Lee et al. (U.S. Patent No. 5,571,523).

Claim 1, from which claim 15 depends, is distinguished above as being patentable over Song and Klokckers-Bethke. While Lee is cited by the Examiner to suggest substitution of one antioxidant for another, Lee does not teach or suggest a coating method that includes isothermally drying the device while the device remains in the solution held in the container. Therefore, Lee does not remedy the noted shortcomings of these other references and thus claim 1 is patentable over the cited combination of all three references. Claim 15 includes the elements of claim 1 and therefore is patentable for at least the same reasons. Claim 15 also includes further distinguishing features. Withdrawal of the rejection is requested.

Applicants respectfully traverse the Examiner's rejection of claim 51 under 35 U.S.C. §103(a) as unpatentable over Song (WO 2005/016399) in view of Klokckers-Bethke et al. (U.S. Patent No. 5,335,769) and further in view of Gao et al. (U.S. Patent No. 6,113,993).

Claim 1, from which claim 51 depends, is distinguished above as being patentable over Song and Klokckers-Bethke. While Gao is cited by the Examiner to suggest coating a device

made of titanium, Gao does not teach or suggest a coating method that includes isothermally drying the device while the device remains in the solution held in the container. Therefore, Gao does not remedy the noted shortcomings of these other references and thus claim 1 is patentable over the cited combination of all three references. Claim 51 includes the elements of claim 1 and therefore is patentable for at least the same reasons. Claim 51 also includes further distinguishing features. Withdrawal of the rejection is requested.

Conclusion

In conclusion, all of the claims remaining in this application are in condition for allowance. A prompt notice to that effect is respectfully solicited. If there are any remaining questions, the Examiner is requested to contact the undersigned at the number listed below.

Respectfully submitted,

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